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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,953	12/10/1998	OYSTEIN FODSTAD	7885.56USWO	8358

7590 03/31/2006

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/125,953	FODSTAD ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2005 and 11 Janaury 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,6-9 and 12-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,6-9 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification contains numerous bibliographic citations, yet it has not been found to contain any statement that the cited documents have been incorporated by reference. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

> Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

Accordingly, the cited documents are not considered to have been incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2, 3, 6-9, and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using

"such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

4. For convenience, claim 12, the sole independent claim currently under consideration, is reproduced below.

12. (Currently Amended) Method for identifying genes differentially expressed between malignant cells isolated from different tissues from the same individual, the method comprising:

(A) detecting malignant target cells from a first tissue and detecting malignant target cells from a second tissue, wherein said first tissue and said second tissue are from the same individual;

(B) obtaining nearly 100% specific first tissue target cells by repeatedly immunomagnetically isolating, *in vitro*, said first tissue target cells and obtaining nearly 100% specific second tissue target cells by repeatedly immunomagnetically isolating, *in vitro*, said second tissue target cells;

(C) determining levels of mRNA expression within said first tissue target cells and determining levels of mRNA expression within said second tissue target cells;

(D) comparing the levels of mRNA expression in said first tissue target cells to the levels of mRNA expression in said second tissue target cells; and

(E) based upon the comparison in step D, identifying the genes differentially expressed between said first tissue target cells and second tissue target cells, in order to recognize ~~previously unknown~~ genes possibly involved in determining metastatic characteristics of cancer cells.

5. For purposes of examination, the claimed method has been interpreted as encompassing the analysis of mRNA sequences, also known as Expressed Sequence Tags, or ESTs. Said method has also been interpreted as encompassing the recognition of genes previously known and unknown, and which may or may not be involved, directly or indirectly, in any metastatic characteristic of any cancer cell in any "individual," which may be human and non-human.

6. Said method has also been interpreted as encompassing the use of immunomagnetic separation means wherein the immuno' portion has virtually any level of specificity. While the method does recite the limitation that repeated passages of immuno-separation are to be performed, the resultant product is no more specific than is the ligand. Accordingly, the cell population, while asserted as being "about 100% specific," is based entirely upon the specificity of the immunoreceptors/ligand, which in and of itself could impart heterogeneity into the cell sample, and into the results obtained.

7. The specification has been found to contain the following examples:

- Example 1, pages 5-6, drawn to physical and enzymatic preparation of tumor cells from primary and axillary nodes from a breast cancer patient.
- Example 2, pages 6-7, wherein cells from a model for experimental metastasis of a human breast cancer were used.
- Example 3, page 7, lines 20-26, MT1 human mammary cancer cells were grown and RNA isolated therefrom.
- Example 4, page 7, last three sentences, prophetic statements that isolated cells can be used for gene cloning purposes.

A review of the disclosure fails to find where any genes have been "recognized" by name by any method, much less the method of claim 12.

8. In accordance with claim 13, the first tissue target cells are malignant cells obtained from solid primary tumors. Applicant's representative, in their response of 23 August 2005, directs attention to Example 2 as disclosing the discovery of genes exhibiting specific expression of MA-11 breast cancer.

9. The foregoing remarks and alleged support have been fully considered and have not been found to constitute an adequate written description of the claimed invention. As an initial matter, it is noted that the cells were not taken from a primary tumor site. Rather, the cells at issue are part of a MA-11 *cell line* that was "established" from micrometastatic tumor cells of a stage II breast cancer patient, and that in accordance with Example 2, the progeny of the cell line were used to infect a murine model. Clearly, the human and murine sources at no time meet the limitation of taking cells from a primary tumor.

10. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

11. At page 7 of the response argument is presented that the application at hand is analogous to Example 18 of the *Revised Interim Written description Guidelines*, and as such, the rejection should be withdrawn.

12. The above argument has been fully considered and has not been found persuasive. For convenience, Example 18 is reproduced below.

Example 18: Process claim where the novelty is in the method steps.

Specification: The specification teaches a method for producing proteins using mitochondria from the fungus *Neurospora crassa*. In the method, mitochondria are isolated from this fungus and transformed with a mitochondrial expression vector which comprises a nucleic acid encoding a protein of interest. The protein is subsequently expressed, the mitochondria is lysed, and the protein is isolated. The specification exemplifies the expression of ∃-galactosidase using the claimed method using a cytochrome oxidase promoter.

Claim:

1. A method of producing a protein of interest comprising;

obtaining *Neurospora crassa* mitochondria,

transforming said mitochondria with a expression vector comprising a nucleic acid that encodes said protein of interest,

expressing said protein in said mitochondria, and

recovering said protein of interest.

In contrast, the claimed method is not directed to the production of a protein from a specific source, rather, the method fairly encompasses the "recognition" of genes that are to be differentially expressed in tumor cells found in virtually any life form capable of generating tumors. Secondly, Example 18 teaches explicitly of the production of a protein of interest, however, in the present case, no protein has been recognized by name, much less shown to be "involved in determining metastatic characteristics of cancer cells."

13. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

14. Claims 2, 3, 6-9, and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

15. The specification has been found to contain the following examples:

- Example 1, pages 5-6, drawn to physical and enzymatic preparation of tumor cells from primary and axillary nodes from a breast cancer patient.
- Example 2, pages 6-7, wherein cells from a model for experimental metastasis of a human breast cancer were used.
- Example 3, page 7, lines 20-26, MT1 human mammary cancer cells were grown and RNA isolated therefrom.
- Example 4, page 7, last three sentences, prophetic statements that isolated cells can be used for gene cloning purposes.

16. A review of the disclosure fails to find where any "previously unknown genes" have been identified by any method, much less the method of claim 1. Additionally, the specification does not identify just what these genes are, or could be. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

17. In view of the extremely limited guidance, the non-disclosure of starting materials and reaction conditions, the aspect that the specification does not reasonably suggest that applicant was in possession of the claimed method at the time of filing, claims 2, 3, 6-9, and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Response to arguments

18. At page 8, bridging to page 9 of the response of 23 August 2005, argument is presented that Example 1 "specifically identifies cell cycle related transcription factor and known oncogene products as genes that were identified by an embodiment of the present invention."

19. This argument has been fully considered and has not been found persuasive. Page 6, lines 16-21, of the specification state:

> Among a number of interesting gene sequences with specific expression either in tumor cells isolated, with our magnetic immunobead technology, from bone marrow or in tumor cells immunomagnetically isolated from lymph node metastases, we have found one cell cycle related transcription factor, one oncogene product, in addition to genes not yet identified. The expression of the two identified gene sequences in biologically relevant model systems and clinical material is presently being analyzed. (Emphasis added)

The specification does not identify which genes have been identified. Rather, the specification states as to the area of their functioning. Further, the specification clearly states that the relevance of these "identified" genes is being evaluated so to determine if they are even relevant. In contrast, the claimed method is to result in the identification of genes "involved in determining metastatic characteristics of cancer cells." The specification is silent as to how what "biologically relevant model systems" are being used, much less how they are adapted for various genes. Clearly, such method steps are crucial to the claimed method resulting in a useful product. And it is also clear, like in the case of *Genentech*, no example is provided as to how this is to be achieved.

Declaration under 37 CFR 1.132

20. The declaration under 37 CFR 1.132 filed 11 January 2006, and previously on 26 August 2002 is insufficient to overcome the rejection of claims 2, 3, 6-9, and 12-14 based upon insufficient written description and non-enablement under 35 USC 112, first paragraph, as set forth in the last Office action because: The showing is not commensurate with the scope of the claims. At page 6 of the declaration argument is presented that one of skill in the art at the time the invention was made would have known how to conduct procedures such as subtractive hybridization and differential display. However, the declaration does not teach how said artisan would be able to collect tissue from a "solid primary tumor" when the tumor is to be of urine, blood, etc. (limitations of claim 2).

21. Included with the declaration is the article entitled *Differential Display Analysis of Breast Carcinoma Cells by Immunomagnetic Target Cell Selection- Gene Expression Profiles in Bone Marrow Target Cells."* At page12 the article states:

> The most prominent disadvantage of the differential display procedure is the high rate of false positives, which need to be screened out by mRNA expression analysis. Unfortunately, confirmation of mRNA expression generally requires larger amounts of mRNA than it is feasible to recover from the likely number of micrometastatic cells obtained by immunoselection.

The specification of the subject application is essentially silent as to how this "prominent disadvantage" is to be overcome.

22. The two PubMed abstract documents (Int. j. Cancer. 2002 Jan 1;97(1):28-33; and Anticancer res. 2002 Jul-Aug; 22(4):1949-57), have been considered and found not to provide convincing evidence that the instant specification satisfies enablement or written description requirements. It is noted with particularity that the documents comprise only abstracts and fail to teach methods used, much less provide citations of where the methods were derived from.

23. The publications of Ree et al., and of Bratland et al., have been considered. It is noted that Bratland et al., teach, "The aim of the study was to examine whether cellular com1 expression may be associated with vitamin D-dependent growth regulation of breast cancer cells." The method does not involve taking cells from solid tumors, but rather, does require the use of MCF-7 and MCF/LCC2 cell lines that have been seeded in experimental media on culture dishes (page 5578, right column).

24. The publication of Ree et al., in stark contrast to the claimed method, calls for the pooling of spinal cords from numerous rats, not the comparison of cells from two tumors found in the same individual. Further, the tumor cells eventually isolated were not from any murine tumor,

but rather, were derived/established from cancer cells isolated from bone marrow of a breast cancer patient.

25. Clearly, these showings are not evidence of enablement, written description, or best mode requirements of 35 USC 112, first paragraph, having been satisfied by the subject application. In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed to be non-enabled by the disclosure.

26. Claims 2, 3, 6-9, and 12-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well-established utility.

27. In order to have utility, the product realized from practicing the claimed method must in turn have a specific, substantial, and credible utility. As presently worded, the method of claims 2, 3, 6-9, and 12-14 is to result in the identification of "genes that are involved in "determining metastatic characteristics of cancer cells." A review of the disclosure fails to find where any gene has been identified by the claimed method. Accordingly, the credibility of the method is in doubt, and the showing made via the Declaration under 37 CFR 1.132 has not been persuasive in removing this rejection and the showings in the publications are not commensurate with the claimed invention.

28. Acknowledgement is made of where at page 1, lines 21-23, the specification states:

> To identify genes **may**, therefore, be of great importance in the understanding of the mechanisms of metastasis and thereby provide new leads or clues for diagnosis or therapy. (Emphasis added)

Said statement, is clearly forward-looking and lacks the specificity and credibility that utility existed at the time of filing.

In accordance with the claims, one is to isolate mRNA and determine its level of expression. Such method steps are highly analogous to the isolation of expressed sequence tags for which no known utility exists, which is in turn analogous to Example 9 of the *Utility Guidelines*. It matters not whether the claim is drawn to a product or process; the claim must be drawn to an invention that satisfies the utility requirements as set forth under 35 USC 101 and as further developed in the Utility Guidelines. To the extent that the claim may result in identification of a gene that is "**possibly** involved in determining metastatic characteristics of cancer cells," such a method is highly analogous to the holding in *Brenner, Comr. Pats. v. Manson*, 148 USPQ 689 (US SupCt 1966):

> Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, 22 without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.
>
> * * *
>
> We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. 24 That

> proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.
> This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. (Emphasis added)

While the claimed invention is drawn to a method and not to a product, the method finds its utility as a result of the product (genes) identified. However, the specification and subsequent showings fail to provide evidence that the claimed invention had utility at the time of filing.

29. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

30. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

31. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
28 March 2006